STERILIZATION GUIDELINES

THIRD EDITION
2020

REFERENCE

ICRC

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Generic sterilization tent

INTRODUCTION

The ICRC has been providing medical and surgical care for the war-wounded since its inception. From humble beginnings, the ICRC has grown to support many large-scale health programmes around the world that provide medical and surgical care for victims of war. These activities include:

- providing support to local hospitals through the presence of expatriate teams, with a strong focus on training and capacity-building
- supplying medicines and equipment
- renovating infrastructure, water and sanitation facilities.

All health-care facilities and hospitals must be able to clean, disinfect and sterilize their equipment and supplies. This process is a crucial part of infection, prevention and control and is essential for providing high-quality care to all patients.

While many books and manuals have been published on sterilization in health-care facilities, they are mostly produced by and for high-income countries and are not appropriate to humanitarian war surgery or staff working with very limited resources.

In 2004 a workshop was held for senior ICRC operating theatre (OT) nurses and experts from Médecins Sans Frontières (MSF) to discuss the main issues relating to sterilization in the context of humanitarian operations. This workshop led to the drafting of the first edition of the *Sterilization Guidelines*. A major review and update was carried out in 2014. Now, it is again time to ensure that our guidelines are up to date with current global practices and that they are appropriate for all our health facilities around the world.

When these guidelines were initially written, they were for a typical ICRC weapon-wounded and emergency surgery hospital in a low-resource setting. In the intervening years, the type of hospital projects that we are involved in has diversified; for instance, we work in secondary and tertiary level care in middle-income countries, countries that are in protracted conflicts, and areas affected by urban violence. While all health-care facilities differ in their design, layout and availability of resources, these guidelines were developed so they can be adapted to the many different settings where the ICRC is present.

While these guidelines were developed for all staff, special consideration was given to nurses on their first field assignment. We recognize that when nurses complete their perioperative training, they may not have had the opportunity to gain a full understanding of how the sterilization process works. These guidelines provide information about the sterilization process and how to put this into practice in precarious circumstances where resources are limited. They can also be used to provide essential training for OT nurses and other staff involved in the sterilization process.

The overall aim of these guidelines is to provide all staff with evidence-based guidance on how to implement and perform the disinfection and sterilization process of medical equipment while working in low-resource and challenging settings. It may be difficult to fully implement all the systems and procedures; however, they represent good practice and set the standards that we need to achieve in order to ensure a high level of care and safety for all our patients and staff.

ABBREVIATIONS

CEN	European Committee for Standardization
CSSD	Central Sterile Services Department
ICRC	International Committee of the Red Cross
ISO	International Standardization Organization
MSF	Médecins Sans Frontières
OT	operating theatre
PPE	personal protective equipment
TST	time – steam – temperature
WHO	World Health Organization

GLOSSARY OF TERMS

Aseptic: Free from disease-causing contaminants.

Bioburden: The number of viable microorganisms in or on an object that forms on and coats various surfaces.

Biofilm: A thin, resistant layer of microorganisms (e.g. bacteria) that forms on and coats various surfaces.

Check: Visual inspection and manual testing to ensure instruments are intact and perform properly.

Cleaning: Consists of removing organic and non-organic substances trough the physical-chemical action of a detergent combined with a brushing and rinsing action.

Contamination: The presence of a minor and unwanted constituent (contaminant) on a material or in a physical body.

Disinfection: The use of disinfectant solution to destroy or prevent the growth of organisms capable of infection.

High-level disinfection: The elimination of vegetative forms of bacteria and viruses by immersing pre-disinfected and cleaned instruments in a disinfectant solution; used for semi-critical material that cannot tolerate steam sterilization.

Medical device: Any medical equipment used on a patient for the purpose of preventing, detecting, diagnosing or treating a pathology.

Nosocomial infection: Infection acquired in a hospital or other health-care facility.

Packaging: Protecting clean instruments from contamination during handling and after sterilization in order to keep them sterile and protected until they are used.

Pathogen: A bacterium, virus or other microorganism that can cause disease.

Sterile: A medical device is considered sterile and referred to as "sterile" if the possibility that it has been contaminated by viable microorganisms is equal to or less that one in a million (CEN and ISO standards).

Sterilization: A process that destroys all microorganisms (including bacterial spores) on the surface of an object or in a fluid.

CHAPTER 1

GENERAL INFORMATION ABOUT STERILIZATION

Cleaning, disinfection and sterilization are key to preventing the spread of infections. The aim of sterilization is to treat medical equipment and devices in such a way that they can be used safely, and when they are used it does not unnecessarily endanger the patient or the user.

Before an instrument can be used, a whole range of measures must be taken to prevent it from being a danger to the patient. Sterilization is only one link in the chain of activities required to make an instrument sterile at the moment of use. Each link involves specific methods and techniques that prevent contamination of instruments, materials and living tissue.

Health staff in charge of sterilization must have a thorough understanding of:

- the nature of the organisms that cause infection
- the measures taken to limit the spread of disease
- how disease-causing organisms can be destroyed
- how to use sterilization equipment safely and successfully
- the design and operation of sterilization equipment
- all types of sterilization loads, packaging systems and their behaviour when exposed to steam and
- the methods for checking the performance of sterilizers.

To ensure that medical equipment and devices are safely sterilized, it is essential for the person performing this procedure to be well trained. While the systems and procedures outlined in these guidelines may be difficult to achieve in all health facilities in which the ICRC is present, they nevertheless represent best practices in ensuring a good level of safety. This should be an achievable goal in any ICRC-supported health facility.

CHAPTER 2

PRINCIPLES OF CONTAMINATION

Before the sterilization process can start, it is essential that all health staff understand:
- how medical equipment and devices become contaminated
- the different methods of reducing contamination
- how to classify medical and surgical instruments.

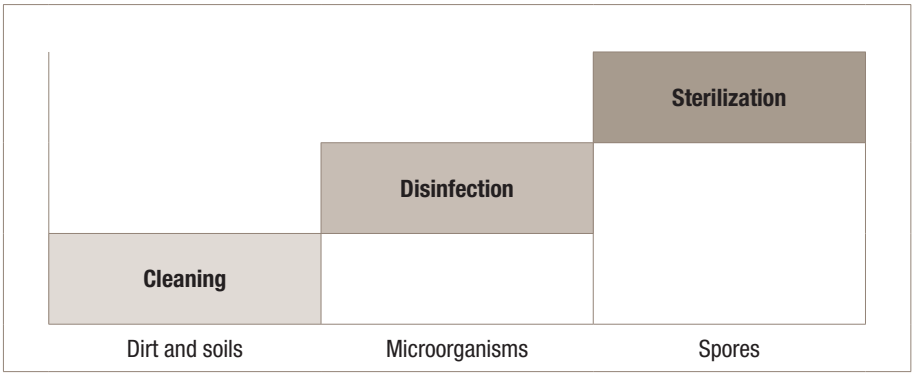
2.1 CONTAMINATION IN HEALTH-CARE SETTINGS

A body penetrated by disease-causing microorganisms is said to be contaminated. Instruments used during an operation are also considered to be contaminated by the patient's microorganisms and pathogens. If these instruments are not scrupulously cleaned and sterilized before being used on another patient, pathogens can be passed from one patient to another. The amount of viable organisms on instruments, linen, materials, etc. is referred to as the bioburden (see Glossary) or initial contamination.

Cross-infections are infections transmitted from one patient to another through contaminated equipment, instruments and/or materials. Cross infection is one of the major causes of nosocomial diseases and can have a significant impact on the patient's outcome, for example:
- extended stay in hospital (potentially leading to further surgery and a complex rehabilitation)
- increased health complications that can ultimately result in death.

2.2 METHODS FOR REDUCING THE BIOBURDEN

All items used within a health-care facility must be clean and free from contamination. The three methods for reducing the bioburden are as follows:



Methods for reducing the bioburden

Cleaning The process of removing dirt and soils, but not killing microorganisms and spores.

Disinfection The process of destroying all pathogenic microorganisms, but not bacterial spores.

Sterilization The process of destroying all forms of microbial life on inanimate surfaces, including bacterial spores.

2.3 SPAULDING CLASSIFICATION

To determine the level of decontamination required for medical equipment and devices, they must first be classified using the Spaulding Classification. In 1968 Dr Earle H. Spaulding classified all medical and surgical equipment based on their potential to spread infections. These categories are as follows:

Critical	Instrument/device that penetrates soft tissue, bone or the vascular system, or through which blood flows.
Semi-critical	Instrument/device that touches mucous membranes or non-intact skin.
Non-critical	Instrument/device that only comes into contact with intact skin.

2.4 CLASSIFICATION OF MEDICAL DEVICES

The appropriate method for reducing the risk of contamination depends on the individual item and the level of decontamination required. Here are some examples using the Spaulding Classification:

SPAULDING CLASSIFICATION	PATIENT CONTACT	METHOD FOR REDUCING THE BIOBURDEN	EXAMPLES
Critical items	Equipment/device that penetrates soft tissue, bone or the vascular system, or through which blood flows	Sterilization	Surgical instruments
Semi-critical	Equipment/device that touches mucous membranes or non-intact skin	High-level disinfection or sterilization	Respiratory therapy equipment Anaesthesia mask
Non-critical	Equipment/device that only comes into contact with intact skin	Low-level disinfection	Blood pressure cuffs Pulse oximeter

CHAPTER 3

ORGANIZING THE STERILIZATION DEPARTMENT

Ideally all hospitals will have access to a Central Sterile Services Department (CSSD) that is able to provide all aspects of instrument/medical device decontamination and sterilization management. This process includes the following steps: collection, pre-disinfection, cleaning, disinfection, packaging, sterilization, validating, distribution and storage of all surgical/medical equipment that is needed for use within the hospital.

In ICRC-supported hospital projects, the preferred option is to set up a CSSD. All surfaces (walls, floors, ceilings, shelves) within the CSSD should be washable and free from cracks or defects. All rooms should be well ventilated and lit. In challenging environments (dust, flies, damaged infrastructure or extreme heat/cold), a balance must be struck between adequate light and ventilation and the potential for contamination of clean material. An uninterrupted supply of water and electricity is essential.

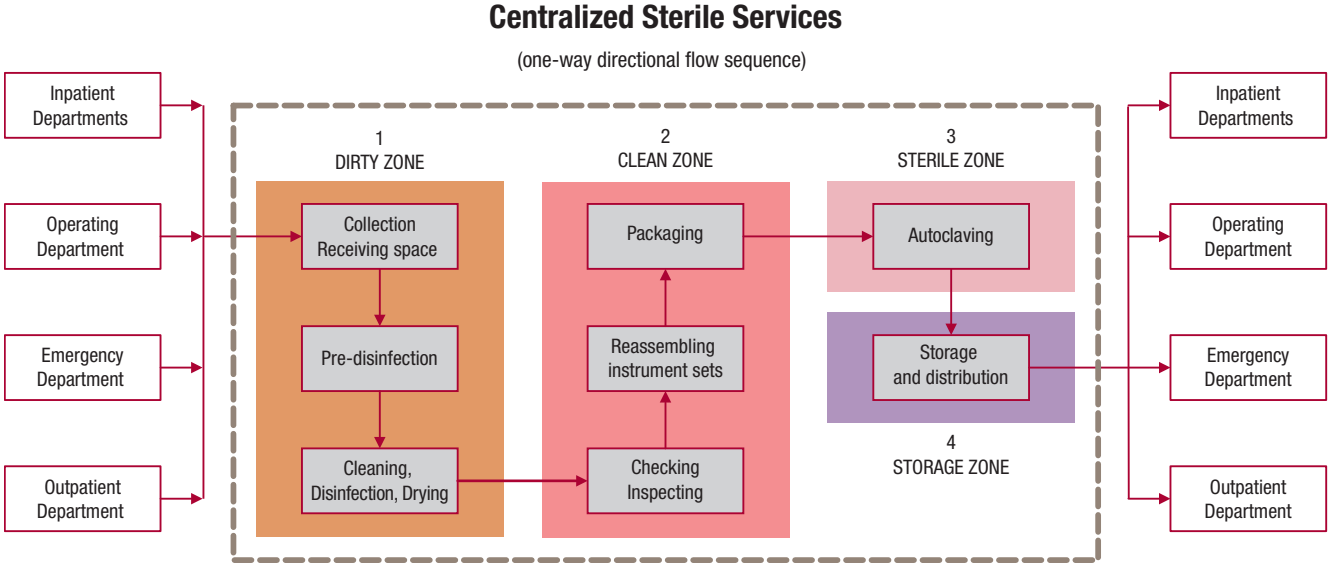
The four stages/activities of the CSSD are:

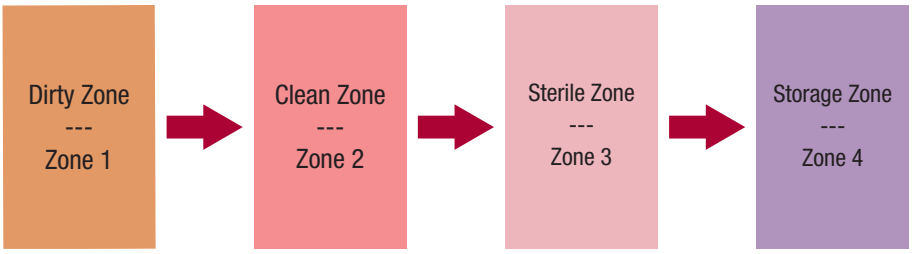
- cleaning (Dirty Zone)
- packaging (Clean Zone)
- autoclaving (Sterile Zone)
- storage and distribution (Storage Zone).

All activities in the CSSD must flow in one direction.

3.1 FLOW OF INSTRUMENTS THROUGH THE CSSD

To prevent contamination, all instruments and all activities carried out in the CSSD must move in one direction only – from dirty to clean. Nothing must move back to the Dirty Zone. Dirty and clean items must never cross.





3.2 ZONE 1 – THE DIRTY ZONE (CLEANING AREA)

The Dirty Zone is where reusable instruments are collected, pre-disinfected, cleaned, disinfected and dried (see Chapter 5 for further information). These activities can be carried out in the same room, provided that the stages are followed sequentially so that all instruments move in one direction only. This room or area should be laid out in a way that facilitates this flow – **nothing should move backwards.** Dirty and clean items must never cross paths.

All items must be checked to ensure they have been properly cleaned before they leave the Dirty Zone. Any items that are not properly clean, must be recleaned before they can leave the Dirty Zone.

→ *The Dirty Zone should be easily accessible from the OT, obstetric and surgical departments to facilitate the reception of reusable instruments. It should be located next to the Clean Zone.*

3.3 ZONE 2 – THE CLEAN ZONE (PACKAGING AREA)

The Clean Zone is the area for checking and inspecting instruments, reassembling instrument sets, packaging and storing packages ready to be sterilized.

Any instruments that are damaged or any incomplete sets should be set aside for the attention of the senior nurse.

→ *The Clean Zone should be located between the Dirty Zone and the Sterile Zone.*

3.4 ZONE 3 – THE STERILE ZONE (AUTOCLAVING AREA)

The Sterile Zone is where the instruments will be sterilized by steam in an autoclave. The type and size of autoclave in a CSSD will depend on the facility.

→ *The Sterile Zone should be located between the Clean Zone and the Storage Zone.*
→ *When using the 90-litre autoclave it must be at least 0.60 m from any other equipment or walls. A steam exit must be provided in line with the manufacturer's specifications (usually created through an exterior wall, with access to outside, to prevent people from being scalded by steam). This access area must be restricted to qualified personnel to prevent scalding.*

3.5 ZONE 4 – THE STORAGE ZONE (STORAGE AND DISTRIBUTION AREA)

The Storage Zone is the area where sterile packages are stored until distributed. It is important to have a storage place in which instruments and sterile items are protected from the risk of recontamination, (i.e. dust, insects, damage to packages, humidity, light) and their sterile status can be maintained until they are needed for use.

→ *The Storage Zone should be located next to the Sterile Zone, ideally in a separate room.*

Storage cabinets

CHAPTER 4

WATER AND ELECTRICITY NEEDS

4.1 WATER REQUIREMENTS FOR THE CSSD

The average amount of water needed in the sterilization room exclusively (not including activities in the OT) is set out below.

AMOUNT OF WATER REQUIRED

Pre-disinfection, disinfection, rinsing and cleaning of instruments

100 litres = 1 x OT procedure (entire instrument load for any type of surgery)
30 litres = 1 x delivery (all instruments for a non-surgical delivery)
30 litres = 5 x dressing sets or 5 x suture sets

Autoclaves

48 litres = 1 x 90-litre autoclave cycle
10 litres = 1 x 45-litre autoclave cycle

Cleaning/disinfection of CSSD and staff hand hygiene

30 litres = Minimum amount per day

Approximately 100 litres of water is needed for every surgical procedure performed in the operating theatre department.

4.2 ELECTRICAL REQUIREMENTS FOR THE CSSD

Voltage stability is critical for the safe installation and running capability of the autoclave. Electrical requirements will vary according to the specific autoclave that you have in your facility and a qualified technician will need to complete an electrical analysis to ensure that the generator or electricity supply is suitable for your CSSD.

4.3 SPECIAL CONSIDERATIONS

Quality of water	Hard water should be avoided as it can lead to a build-up of limescale.
Water temperature	Water used for the autoclave drying cycle must be **cold** (preferably < 25°C).
Specialized equipment	If your facility has a larger style autoclave, this should be installed according to the manufacturer's specification. An ICRC biomedical engineer can advise before installation.

CHAPTER 5

THE STERILIZATION CYCLE

All steps in the sterilization cycle are critical to ensure the safe use of reusable surgical instruments. If any step is preformed incorrectly, the instruments may not be sterile.

To prevent the spread of infection, all steps must be completed in a sequential manner, moving in one direction only from dirty to clean.

Sterilization cycle always flows in one direction.

The sterilization cycle consists of the following steps:

- collection
- pre-disinfection
- cleaning and disinfection
- drying and checking
- packaging
- autoclaving
- control and traceability
- storage.

Points to remember

- If there is any doubt whether a process or step has been done – assume it has NOT.
- Instruments must never move backwards in the sterilization cycle.
- Dirty and clean instruments must not come into contact with each other – keep separate to avoid cross-contamination.
- Do NOT mix surgical instruments and textiles/linen in the same autoclave load.
- It is not recommended to use chlorine to disinfect instruments. But if you have no other options, a chlorine 0.5% solution should be used.

ALL surgical instruments that are opened in the OT, even if they were not used, **MUST** go through every step in the sterilization cycle.

See Appendix I for summary procedure for pre-disinfection, cleaning and disinfecting instruments.

5.1 COLLECTION

All instruments should be collected in perforated baskets and buckets and taken to the CSSD for cleaning.

Aim

To transport contaminated instruments to the CSSD while ensuring staff safety and minimizing the risk of spreading microorganisms in the environment.

Instruments should be collected and pre-disinfected as soon as possible after use. In the OT, instruments must be sent for cleaning after each procedure. On the wards, they should be collected at least twice a day. This is to avoid blood and secretions drying on the instruments and helps decrease the bioburden.

Purpose

Collecting contaminated instruments in baskets and buckets enables safe collection for staff, less handling of the instruments, an easy and safe method of transporting them to the CSSD, less chance of mixing up surgical sets, and they are easily available and inexpensive in local markets. This method also allows for easier and quicker pre-disinfection.

Equipment needed

- Plastic bucket with lid
- Perforated basket – slightly smaller in size so it can fit inside the plastic bucket
- PPE

A. Neville/ICRC

J. Barnet/ICRC

When transporting contaminated instruments to the CSSD the collection bucket **MUST** be empty. There must be **NO** water or pre-disinfection solution in the bucket for transportation to the CSSD.

Technique

- At the end of every procedure or operation, place contaminated instruments in the basket-and-bucket in an open position (except for sharp instruments, e.g. scissors). Transfer the basket-and-bucket to the CSSD as soon as practical.
- A bucket with lid should be kept on the ward for collection of instruments. These instruments should be collected at least twice a day to avoid blood and secretions drying on the instruments.
- The bucket must be empty, no water or pre-disinfection solution, to enable the safe transportation of contaminated instruments – preventing splashes or spills and protecting staff.

5.2 PRE-DISINFECTION

Aim

To reduce of the number of microorganisms on the surface of the instruments via the chemical action of disinfectant.

Purpose

Pre-disinfection is the first step in the sterilization cycle and will reduce the amount of bioburden on the surgical instruments.

Equipment needed

- Sink or basin
- Clean water (for preparing the disinfection solution and for rinsing the instruments)
- Disinfection solution
- Timer
- PPE
- *See Appendix II & III for instructions on the preparation of disinfection solution.*

U. Sadiq/ICRC

C. Donald/ICRC

Instruments/medical equipment should be pre-disinfected as soon as possible after use to prevent the formation of biofilm.

Technique

- Prepare a soaking bath with disinfection solution according to the volume of surgical instruments (5 litres or 10 litres).
- Instruments must be completely immersed in the soaking bath for 15 minutes. **Use a timer**. The instruments must be in the open position to ensure that the instrument has maximum contact with the disinfectant solution.
- Flush any hollow instruments with the disinfection solution – e.g. use a clean syringe to flush the poole sucker.
- Rinse all instruments with clean water.
- Throw away the used solution and prepare a fresh bath for the next load of instruments.

ALL surgical instruments that are opened in the OT, even if they were not used, **MUST** go through every step in the sterilization cycle.

5.3 CLEANING AND DISINFECTION

Aim

To reduce the amount of bioburden (blood, secretions and debris) on contaminated surgical instruments via the chemical action of disinfectant combined with the mechanical action of brushing and rinsing.

Purpose

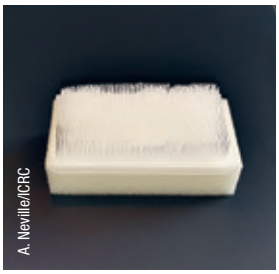
Cleaning is an essential step of the sterilization cycle as it reduces the amount of bioburden on the contaminated instruments. If this step is not carried out correctly, the steam sterilization process may be ineffective.

Instruments and equipment must be thoroughly cleaned and disinfected, otherwise the sterilization process will not be effective.

Equipment needed

- Sink or basin
- Clean water (for preparing the disinfection solution and for rinsing the instruments)
- Disinfection solution
- Different sizes of cleaning brushes
- Timer
- PPE
- *See Appendix II and III for instructions on how to prepare disinfection solution.*

This solution can be kept for a maximum of 24 hours. Prepare a fresh bath immediately if it is visibly contaminated (i.e. dirty).



Technique

- Prepare a soaking bath with disinfection solution according to the volume of medical instruments (5 litres or 10 litres).
- Instruments must be completely immersed in the soaking bath of disinfection solution.
- **Each instrument must be individually scrubbed** with an appropriate size cleaning brush.
- Flush any hollow instruments with the disinfection solution – e.g. use a clean syringe to flush the poole sucker.
- After manually cleaning each instrument, they must all be completely immersed in the disinfection solution and left to soak for 15 minutes. **Use a timer**.
- Rinse all instruments with clean water.

The solution can be kept for a maximum of 24 hours; however, if it becomes visibly contaminated, prepare a fresh bath for the next load of instruments.

5.4 DRYING AND CHECKING INSTRUMENTS

Aim

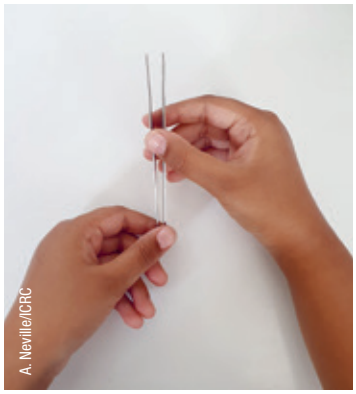
To dry all the surgical instruments carefully and correctly while checking they are free from any contamination and are in good working order.

Purpose

All items must be carefully dried and checked before undergoing sterilization. If they are not cleaned correctly, corrosion (rust) may develop, which is then aggravated by the moisture and high temperatures of the sterilization process. This corrosion may result in serious damage to the instrument and could potentially make them unusable or dangerous for the patient. This is why every instrument must be carefully checked before being packed.

Equipment needed

- Flat workspace e.g. large table or bench
- Clean reusable drape or single use surgical drape (to cover the workspace)
- Lint-free cotton cloth



Technique

- Cover the workspace with a drape to protect the instruments from getting contaminated. This drape must be changed every day.
- All the instruments must be laid out in the open position to dry.
- It is important to try and not mix the instruments sets.
- Wipe each instrument with a clean, lint-free cloth.
- Take special care of hollow instruments – a clean syringe filled with air can be used.
- As each instrument is hand dried, it must be checked to ensure it is in good working order and not missing any parts.
- If any of the instruments are damaged, no longer functioning or missing, the senior OT nurse must be alerted so that appropriate action can be taken.
- Each set is then re-assembled in its kidney dish or instrument tray.
- Apply silicone-free instrument oil as required. The instrument should then be rinsed in clean water to remove any excess oil and dried.

The instruments are now ready to be wrapped and packaged for sterilization.

5.5 PACKAGING

Aim

Packaging must be permeable to steam, water repellent, resistant to tears and impermeable to microorganisms. The packaging protects the clean instruments from the risk of contamination before sterilization and keeps them sterile until they are used. The packaging must also be able to be opened easily and aseptically.

Purpose

Correct packaging of the instruments allows safe sterile storage of the instruments until they are required for use.

Equipment needed

- Flat workspace e.g. large table or bench
- Clean reusable drape or single use surgical drape (to cover the workspace)
- Sterilization paper
- Autoclave tape
- Class 6 TST (time – steam – temperature) strip
- Marker pen specifically for use in an autoclave
- Scissors

The ICRC has two types of paper that is used to wrap surgical instruments and equipment:

Non-woven paper	Instruments that are in large wire baskets are to be wrapped in two layers of non-woven paper (stronger than crepe paper). These must be wrapped with two single sheets.
Crepe Paper	Crepe paper should be used for smaller items, such as single instruments, diathermy devices, dressing sets and "fluffy gauze".

Technique

- Cover the workspace with a drape to protect the instruments from getting contaminated. This drape must be changed every day.
- Select the type of sterilizing paper that is appropriate for the instruments you want to wrap.
- The paper must be at least 3 to 4 times the size of the total equipment to be packed (in both width and length).
- Use the American square or envelope folding technique for both layers.
- Close the package carefully using sterilization tape.

Once the paper has been autoclaved, it cannot be re-autoclaved. The filters in the paper are closed by the first sterilization and are therefore not re-autoclavable.

See Appendix IV and V for visual instructions on the American folding technique and how to fold surgical gowns.

S. Latam/ICRC

N. Moon/ICRC

A. Neville/ICRC

5.6 SATURATED STEAM STERILIZATION – THE AUTOCLAVE

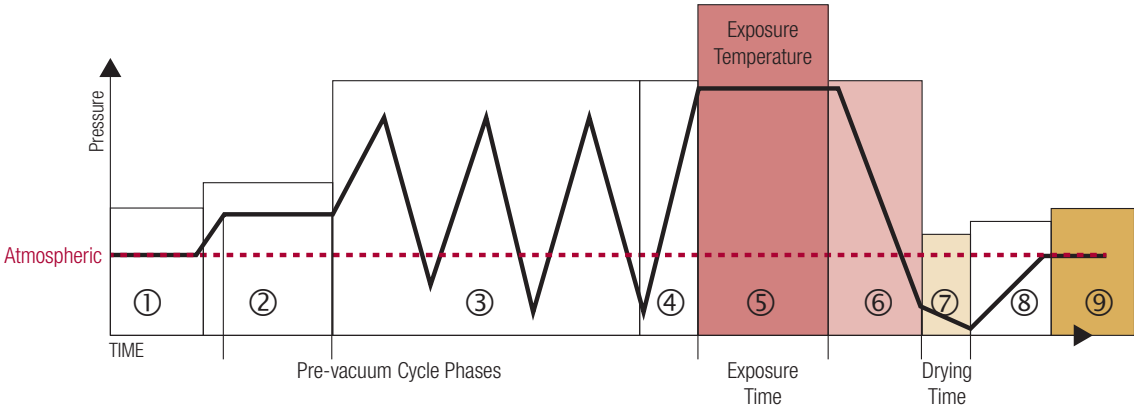
5.6.1 GENERAL INFORMATION

The sterilization of medical equipment and devices using steam and pressure is a reliable method of destroying all forms of microorganisms. Three parameters are required to achieve successful sterilization: temperature, steam pressure and time. To achieve this, you must have a good understanding of how the autoclave works and be able to operate it correctly and safely. The steps recommended by the manufacturer must be followed exactly, otherwise the sterilization process will be incomplete (see appendices VI, VII, VIII, IX & X).

- An autoclave is essentially a large pressure cooker; it operates using steam under pressure as the sterilizing agent. The high pressure it generates heats the steam to very high temperatures, therefore increasing its heat content and killing power.
- Steam is able to penetrate objects with cooler temperatures. This is because when the steam comes in contact with a cooler surface, it immediately condenses to water. This creates negative pressure at the point of condensation and draws more steam to the area. Condensation continues for as long as the condensing surface is cooler than the steam. Once both are the same temperature, a saturated steam environment is formed.
- Achieving a high and even moisture content in the steam-air environment is important for effective autoclaving. This is because steam efficiently kills cells and coagulates proteins. This moist heat is thought to kill microorganisms by causing coagulation of essential proteins. The microorganisms then die because of an accumulation of irreversible damage to all their metabolic functions.

5.6.2 THE STEAM STERILIZATION CYCLE

The steam sterilization cycle consists of nine phases.



1. Start	Close the autoclave lid; the chamber will begin to warm.
2. Heating	As the water warms, steam will enter the chamber and start to purge the air.
3. Purge	Positive pressure and negative vacuum pulses will purge air from the chamber (to eliminate all air pockets).
4. Heating	The pressure will increase to 2.2 bar (134°C).
5. Sterilization	Start the timer for the sterilization cycle (18 or 25 minutes).
6. Expelling	The chamber drain is opened; steam and boiling water will be expelled.
7. Drying	Cool water will create a vacuum in the chamber; the drying time is 30 minutes.
8. Air in	The chamber will return to atmospheric pressure.
9. Cycle complete	Open the autoclave lid.

5.6.3 STERILIZATION CYCLE TEMPERATURE

Autoclave cycle temperature and time	
Instruments	134°C at 2.2 bar for 18 minutes
Textiles/linen	134°C at 2.2 bar for 25 minutes

5.6.4 SAFETY

Autoclaves use steam, heat and pressure, which significantly increases the risk of potentially having an accident. All staff MUST wear PPE when unloading the autoclave, i.e. heat-resistant gloves, heat-resistant aprons and eye protection.

Do not assume that the temperature and pressure has fallen when opening the autoclave. Even if the pressure gauge shows "0", open the autoclave lid carefully; start by opening the lid a very small amount to allow any steam to dissipate. Do NOT fling open the lid – it MUST be done slowly and gently, as otherwise steam may billow out and scald you.

After opening the autoclave lid, leave the packages inside for five minutes before handling. This will reduce the risk of scalding.

The autoclave must be regularly inspected to ensure that it is working correctly. A trained technician must follow the maintenance schedule as recommended by the autoclave manufacturer.

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5.6.5 THE END OF THE AUTOCLAVE CYCLE

- When unloading the packages/instrument sets at the end of the cycle they must be checked to ensure that they are undamaged.
- The packages should not be damp or wet and the paper must be intact. Inspect each package for tears or holes.
- Any torn or damaged packages are unsterile and must be sent for repackaging and resterilization.

5.7 CONTROL AND TRACEABILITY

5.7.1 CONTROL

Purpose

For every sterilization load, we must be able to prove that the autoclave worked properly and that the sterilization cycle achieved the required standards. The ISO and the CEN recommend recording the physical conditions (or parameters) in the sterilizer during the process.

Equipment needed

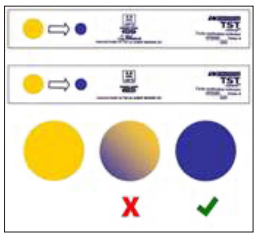
Two methods are used for every sterilization cycle to check that it processed correctly:

- Chemical indicator = Class 6 TST strip
- External indicator = autoclave tape

Technique (Both 1 & 2 must be done for every sterilization cycle.)

1. Class 6 TST strip – Chemical indicator

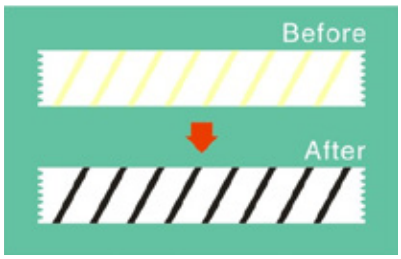
- TST strip indicators undergo a chemical change (from yellow to dark blue) when exposed to steam and temperature over time.
- A Class 6 TST strip must be put in all surgical sets to monitor the time, steam and temperature inside the packages. This is not needed for small sets, e.g. dressing, suture and delivery sets.
- A Class 6 TST strip, wrapped in a double layer of crepe paper, must be placed in the middle of the autoclave load to monitor the steam and temperature inside the chamber.
- **Important:** After the sterilization cycle is completed, and before the instruments are sent to the storage room, you MUST confirm that the Class 6 TST strip has changed colour. If it has not, the complete load must be considered unsterile and sent for repackaging and resterilization.



Make sure you choose the correct control strip for the sterilization cycle you want to do. e.g. Class 6 TST strip 134°C – 18 min.

2. Autoclave tape – External indicator

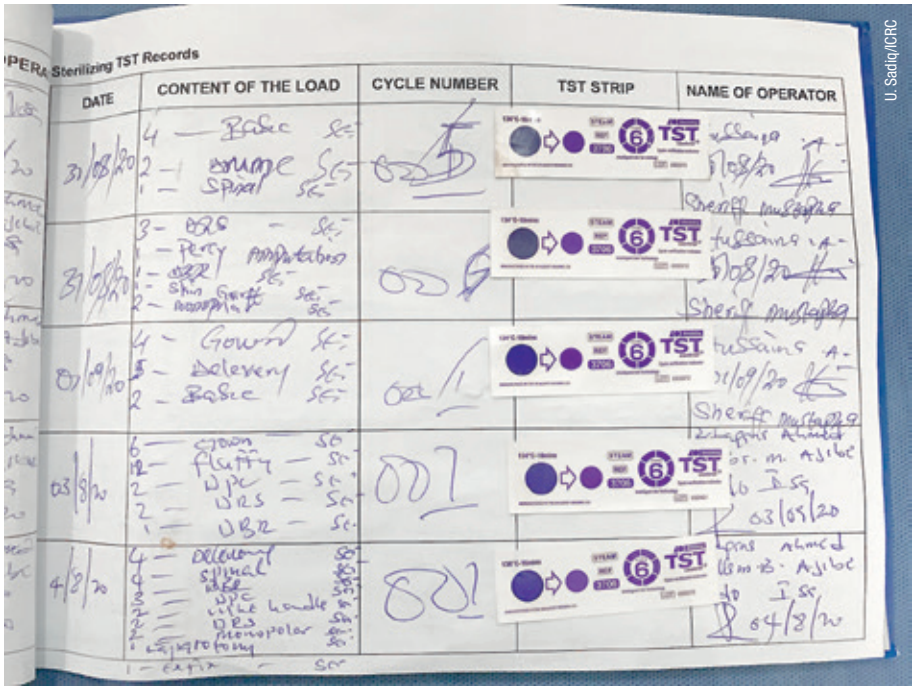
- Autoclave tape indicators are used **only to identify** packages that have been through the steam sterilization process.
- Autoclave tape consists of yellow indicator stripes and pressure-sensitive adhesive. The colour of the indicator strips will turn from yellow to dark brown/black once it has been through the steam sterilization process.



5.7.2 TRACEABILITY

Each sterilization cycle must be recorded in a logbook, with each individual autoclave having its own individual book. The logbook must contain the following information:

- date
- contents of the load
- cycle number
- the Class 6 TST control strip
- the name of the person who carried out the sterilization cycle.



5.8 STORAGE AND EXPIRY

It is most important to maintain the integrity and sterility of all packages until they are used. All equipment should be stored in such a way as to allow an inventory to be properly managed and expiry dates to be monitored.

5.8.1 STORAGE

The storage room should be clean, closed and well ventilated. Ideally this room should be restricted to OT staff only or at a minimum be a room that has few people passing through.

Sterilized packages should be stored away from dust, humidity and sunlight. To further ensure the integrity of sterilized packages, it is recommended that they be stored in closed cabinets and/or plastic storage boxes with lids (readily available in the local market). Dust covers are included in the medical surgical team kits.

5.8.2 EXPIRY

The length of time materials remain sterile depends on the quality of the entire sterilization process, the quality of the packaging and the quality of storage. If the storage conditions described above are respected and items are double-wrapped in crepe paper or non-woven sheets, they can be stored for a **maximum of four weeks** before they expire.

The instruments should **NOT** be placed in plastic boxes or dust covers straight after the sterilization process.

Packages first need to cool down, preferably on a wire rack. Care should be taken not to damage the packaging.

5.8.3 EXPIRY CHECKING

Expiry dates must be checked once a week and recorded in a logbook.

5.8.4 STOCK MANAGEMENT

Important rule: first in, first out. Always use the items that are due to expire first.

Stock rotation is an important part of the weekly check. During the weekly check, all packages must be checked for their expiry date, with those expiring sooner to be brought to the front and those with later expiry dates moved to the back. Packages must also be checked to ensure they are free from damage, e.g. rips or tears in the paper.

F. Aruni Ombeni/ICRC

A.Neville/ICRC

CHAPTER 6

EMERGENCY STERILIZATION

Emergency sterilization should ONLY be employed as a last resort if surgical instruments cannot be sterilized because of autoclave failure.

Instruments that have undergone high-level disinfection are NOT considered sterile. High-level sterilization is therefore a last resort, and for life-saving circumstances only.

6.1 WHAT IS EMERGENCY STERILIZATION?

Emergency sterilization is high-level disinfection employed when an autoclave has failed and surgical instruments are needed for a life-saving procedure. It is only a temporary solution.

6.2 OPERATING WITH INSTRUMENTS USING THE EMERGENCY STERILIZATION PROCEDURE

The surgeon must be informed immediately, and it is ultimately their decision whether or not to proceed. If they decide that the life-saving surgery/procedure must go ahead, despite the risk to the patient, this must be noted in the patient's medical file. Semi-elective or elective surgery should **not** be performed under these conditions.

6.3 EMERGENCY STERILIZATION PROCEDURE

Senior ICRC health staff, including but not limited to: OT nurse, surgeon, hospital project manager, and any other relevant support staff should be immediately informed. An action plan to correct the problem must be developed and implemented.

6.4 EMERGENCY PREPAREDNESS

In case of autoclave failure, you should always be prepared by having the following items in stock:

Surgical drapes and gowns	A supply of sterile single use surgical drapes and gowns. A supply of reusable (cloth) surgical gowns and drapes should always be available. Using reusable drapes and gowns is not ICRC standard practice. However, they should always be available for life-saving procedures, in case of an emergency (e.g. issues with logistics and receiving new supplies).
Abdominal packs and gauze	A supply of sterile abdominal packs and gauze.
Surgical instruments	The OT nurse must always know how many surgical instruments sets they have in their department, how many are sterile and how many need to be sterilized.

Having these emergency items always available will allow life-saving procedures to be carried out in the event of autoclave failure without compromising patient safety.

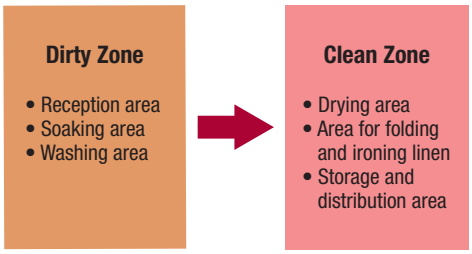
CHAPTER 7

HOSPITAL LAUNDRY AND THE STERILIZATION PROCEDURE FOR LINEN

Contaminated linen is generated by all departments within hospitals. The process of laundering linen (including clothing/scrubs) is done in three steps: soaking, washing and disinfection. This is necessary to prevent cross infection from the use of reusable linen. The nature of the soiling will determine how it is sorted and processed.

7.1 ORGANIZING THE LAUNDRY

To prevent the spread of infection, clean and dirty linen should always be separated. The process of cleaning soiled linen must start in the Dirty Zone and progress to the Clean Zone. This is a one-way process, with no possibility of the linen crossing each other. The Clean Zone and Dirty Zone should be separated.



7.2 AIM

To collect linen used in the OT and on the wards and take it to the washing area of the laundry while ensuring staff safety and minimizing the risk of spreading microorganisms.

The aim of washing linen is to remove soiling via the chemical action of soap combined with the mechanical action of brushing, followed by rinsing and disinfecting. Linen to be sterilized before use needs to be carefully cleaned before going into the autoclave. The sterilizing procedure is the same as for the sterilization of instruments, except the cycle is for 25 minutes at 134°C.

Disinfecting laundry

0.05% chlorine solution must be used to disinfect laundry.

7.3 EQUIPMENT NEEDED

- Laundry area with a dirty zone and a clean zone
- Washing machine and dryer or washing basins and space to dry linen
- Receptacles to collect soiled linen:
  - leak-resistant container or plastic bag for "wet linen" (linen soiled with organic matter, e.g. blood, faeces, mucus)
  - cloth bag for "dry linen" (soiled but visibly clean linen)
- Water, washing detergent, chlorine and PPE

See Appendix XI for instructions on how to prepare a 0.05% chlorine solution.

7.4 COLLECTION OF CONTAMINATED LINEN

All linen must be washed as quickly as possible after delivery to the laundry. Ideally two bags should be available:

- **one for wet linen**, i.e. linen soiled with organic matter (e.g. blood, faeces, mucus), preferably a leak-resistant container or plastic bag
- **one for dry linen**, i.e. soiled but visibly clean linen, preferably a cloth bag.

Collecting linen from the OT

All used linen must be collected as soon as possible at the end of each operation. All linen MUST be checked for sharps.

Collecting linen from the wards

All used linen must be collected at least once a day from each ward (including changing rooms). All linen MUST be checked for sharps.

Collection of linen

7.5 PROCEDURE FOR SOAKING, WASHING AND DISINFECTING CONTAMINATED LINEN

All staff must wear heavy-duty, long rubber gloves, a waterproof apron and eye protection when handling contaminated linen. The soaking, washing and disinfecting of contaminated linen can be done either by hand or by using a washing machine. The preferred method is to use a washing machine.

WASHING BY HAND

Linen is in the Dirty Zone

If the linen is soiled but visibly clean, the washing process starts at step 3.

1. Empty the dirty linen into the laundry sink or washing basin, ensuring there is enough cold water to immerse the linen completely. Linen which is soiled with organic matter or blood must soak for 30 minutes. Stir occasionally with a stick to loosen the debris.
2. After soaking linen for 30 minutes, remove it from the laundry sink or washing basin.
3. Fill a laundry sink or washing basin with warm (i.e. heated to body temperature), soapy water.
4. Immerse the linen completely and scrub with a brush.
5. Remove the linen from the soapy water and rinse with copious amounts of running water (until the soap is completely washed out).
6. Drain the dirty water into the wastewater system.
7. Prepare a 0.05% chlorine solution for disinfecting the linen in a non-metal bucket.
8. Immerse the linen completely in the solution and let it soak for 15 minutes.
9. Rinse copiously, at least three times, to wash out the chlorine.
10. Drain the chlorine solution into the wastewater system.
11. Wearing clean gloves and apron, the linen must be wrung out and then placed into a clean/dry bucket for transporting to the drying area.

Linen is now in the Clean Zone

12. Hang the linen to dry on a clothesline in an area that is protected from rain, insects and dust (or use a clothes dryer, if available).
13. Transport the dry linen to the ironing and folding area of the laundry.

USING A WASHING MACHINE

Linen is in the Dirty Zone

If the linen is soiled but visibly clean, the washing process starts at step 2.

1. Put the dirty linen into the washing machine on a pre-wash cycle at a low temperature (below 25°C) for 5 to 7 minutes.
2. Wash the linen on a full wash cycle at 60°C (60°C for 15 minutes to achieve thermal disinfection).
3. Run another rinse cycle.
4. Prepare a 0.05% chlorine solution for disinfecting the linen. Add to the washing machine's dispenser.
5. Disinfect for 5 minutes.
6. Run a rinse cycle three times with clean water to wash out the chlorine.
7. Run a spin cycle.
8. At the end of the wash cycle, put on clean gloves and apron to empty the machine into a clean and dry bucket for transporting to the drying area.

Linen is now in the Clean Zone

9. Hang the linen to dry on a clothesline in an area that is protected from rain, insects and dust (or use a clothes dryer, if available).
10. Transport the dry linen to the ironing and folding area of the laundry.

Points to remember

- If your facility has an industrial washing machine, the linen should be washed at 60°C on a full cycle.
- Do not leave damp linen or clothing in the washing machine overnight.
- Be careful not to overload the machine; follow the manufacturer's recommendations.
- If using a clothes dryer, do not leave unattended while it is running as it may overheat.
- The washing machine must be regularly serviced by a trained technician.

7.6 DRYING AND FOLDING CLEAN LINEN

Drying the clean linen can be done on either a clothesline or clothes dryer. Once it is completely dry, take it to the Clean Zone of the laundry area for ironing and folding.

After drying, the linen must be inspected for wear and tear. If repairs are needed, it should be taken out of use until it is repaired.

Once the linen has been ironed and folded, it should either be stored in the dedicated linen cupboard or prepared for sterilization.

7.7 PACKAGING, STERILIZATION AND STORAGE

If linen, surgical drapes or surgical gowns are to be sterilized, they must be wrapped in two layers of crepe paper (after it has been ironed and folded). The process for sterilization of linen is the same as surgical instruments; the cycle must be for 25 minutes.

See Appendix V for instructions on how to fold reusable surgical gowns.

Sterilization process for linen
Sterilization cycle for linen: 134°C for 25 minutes. Do **NOT** put linen and surgical instruments in the same sterilization load.

Drying laundry

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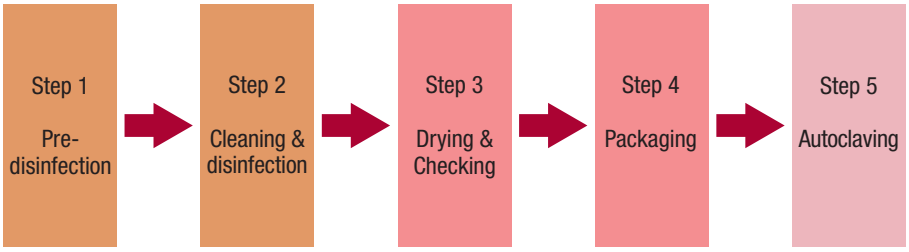
APPENDIX I
SUMMARY OF PRE-DISINFECTION, CLEANING, DISINFECTING AND AUTOCLAVING OF SURGICAL INSTRUMENTS



1. Pre-disinfection

From the OT: As soon as the surgery/procedure has finished, take the instruments straight to the CSSD. Immerse the instruments completely in the pre-disinfection soaking bath and soak for 15 minutes. Use a timer. Rinse with clean water.

From the wards: Collect the instruments in a perforated basket-and-bucket and take to CSSD. Immerse the instruments completely in the pre-disinfection soaking bath and soak for 15 minutes. Use a timer. Rinse with clean water.

ONE patient = ONE soaking bath

This pre-disinfection solution must be changed after each use (i.e. after each operation).

2. Cleaning and disinfection

Immerse the instruments completely in the disinfection soaking bath, brush each instrument thoroughly and soak in the solution for 15 minutes. Rinse thoroughly with clean water.

3. Drying and checking

The instruments must be dry before packaging. Wipe each instrument dry with a clean, lint-free cloth. Inspect all instruments to ensure they are in good working order and not missing any parts.

4. Packaging

Instruments are wrapped in either non-woven paper or crepe paper.

Non-woven paper should be used for instruments that are in large wire baskets. They must be wrapped in two layers of non-woven paper (stronger than crepe paper).

Crepe Paper should be used for smaller items such as single instruments, diathermy devices, dressing sets and “fluffy gauze”.

Steam indicator tape: Close each package with autoclavable indicator tape.

A Class 6 TST strip must be put in all surgical sets to monitor the time, steam and temperature inside the packages. This is not needed for small sets, e.g. dressing, suture and delivery sets. A Class 6 TST strip, wrapped in a double layer of crepe paper, must be placed in the middle of the autoclave load.

5. Autoclave sterilization

Do not put linen and instruments in the same load. They MUST be sterilized separately.

Instrument cycle: 134°C for 18 minutes

Textile/linen cycle: 134°C for 25 minutes

6. Traceability

Complete the sterilization logbook: attach the control Class 6 TST strip and write the date, cycle number, type of load, signatures and any comments.

7. Expiry date

Write the sterilization date on the steam indicator tape with a marker. Items double-wrapped in crepe paper or non-woven sheets can be stored for a **maximum of four weeks** before they expire.

APPENDIX II
INSTRUCTIONS FOR PREPARING HEXANIOS

Hexanios is a detergent-disinfectant used to pre-disinfect, clean and disinfect reusable instruments (surgical instruments and small medical devices/equipment).

Concentrated Hexanios solution must be diluted to **0.5%** for use as a disinfectant in the CSSD.

Equipment needed

- Sink or basin
- Clean water (for preparing the disinfection solution)
- Hexanios disinfection solution
- Timer
- PPE – apron, gloves, mask and goggles must always be worn when using this product

Avoid contact with skin and eyes; in case of contact, rinse immediately and thoroughly with clean water and seek medical advice.

Technique for preparing Hexanios solution

1. In a sink or basin put 5 litres or 10 litres of clean water (enough to immerse the instruments).
2. Add the Hexanios concentrate in accordance with the dosing table below.
3. Stir until the solution is completely mixed.
4. Set the timer for 15 minutes.
5. After 15 minutes, the Hexanios solution is ready to be used.

After the Hexanios concentrate has been mixed in, the solution **MUST** rest for 15 minutes before it can be used.

DOSING TABLE TO PREPARE 0.5% HEXANIOS DISINFECTION SOLUTION USING CONCENTRATED SOLUTION

Amount of disinfection solution required	Amount of concentrated Hexanios
5 litres	25 ml (1 stroke of dosing pump)
10 litres	50 ml (2 strokes of dosing pump)
20 litres	100 ml (4 strokes of dosing pump)
30 litres	150 ml (6 strokes of dosing pump)

Hexanios solution – pre-disinfection
- Do **NOT** reuse the solution.
- It must only be used for one load of instruments.

Hexanios solution – cleaning and disinfection
- Can be used to disinfect multiple loads of instruments.
- Can be kept for a maximum of 24 hours.
- If it becomes visibly dirty, a new solution must be prepared.

APPENDIX III
INSTRUCTIONS FOR PREPARING NEODISHER SEPTO ACTIVE

Neodisher Septo Active is a detergent-disinfectant used to pre-disinfect, clean and disinfect reusable instruments (surgical instruments and small medical devices/ equipment).

Neodisher Septo Active must be diluted to **2%** concentration for use as a disinfectant in the CSSD.

Equipment needed

- Sink or basin
- Clean water (for preparing the disinfection solution)
- Neodisher Septo Active disinfection solution
- Timer
- PPE – apron, gloves, mask and goggles must always be worn when using this product

Avoid contact with skin and eyes; in case of contact, rinse immediately and thoroughly with clean water and seek medical advice.

Technique for preparing Neodisher Septo Active solution

1. In a sink or basin put 5 litres or 10 litres of clean water (enough to immerse the instruments).
2. Add the amount of Neodisher Septo Active granulates in accordance with the dosing table below.
3. Stir until all the granulates are completely dissolved.
4. Set the timer for 15 minutes.
5. After 15 minutes the Neodisher Septo Active solution is ready to be used.

After the Neodisher Septo Active granulates have been dissolved, the solution **MUST** rest for 15 minutes before it can be used.

DOSING TABLE TO PREPARE A 2% NEODISHER SEPTO ACTIVE DISINFECTION SOLUTION USING THE NEODISHER DOSING CAP

Amount of disinfection solution required	Amount of concentrated Neodisher
5 litres	125 ml
10 litres	250 ml
20 litres	500 ml
30 litres	750 ml

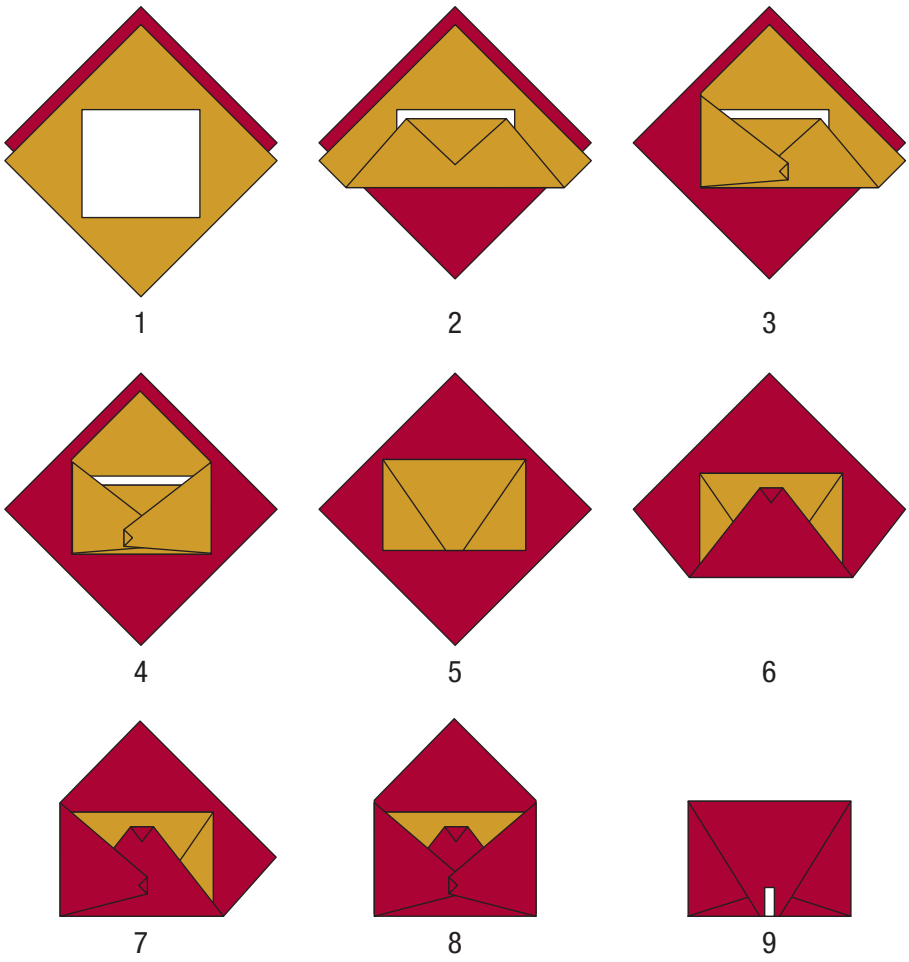
DOSING TABLE TO PREPARE A 2% NEODISHER SEPTO ACTIVE DISINFECTION SOLUTION USING SACHETS (1 SACHET = 100 G)

Amount of disinfection solution required	Amount of concentrated Neodisher
5 litres	1 sachet (100 g)
10 litres	2 sachets (200 g)
20 litres	4 sachets (400 g)
30 litres	6 sachets (600 g)

Neodisher Septo Active solution – pre-disinfection
- Do **NOT** re-use the solution.
- It must be used for one load of instruments only.

Neodisher Septo Active solution – cleaning and disinfection
- Can be used to disinfect multiple loads of instruments.
- Can be kept for a maximum of 24 hours.
- If it becomes visibly dirty, a new solution must be prepared.

APPENDIX IV
VISUAL INSTRUCTIONS FOR THE AMERICAN FOLDING TECHNIQUE



APPENDIX V
INSTRUCTIONS FOR FOLDING A SURGICAL GOWN

1. Use a **flat workspace**, e.g. a large table or bench.
2. Lay the **inside** of the gown face **down.**
3. Cross the two sleeves on the **upper** part of the gown (chest).
4. Tie the two thick outside fasteners together loosely.
5. Fold over the **closest** shoulder, so that the seam is visible all the way down the gown.
6. Adjust the **opposite** shoulder, so that the seam is visible all the way down the gown.
7. Ensure that the two top and two inside fasteners are towards the bottom of the gown.
8. Fold the **closest** part of the gown, keeping 3 centimetres **away** from the collar.
9. Fold the **opposite** part of the gown, keeping 3 centimetres **away** from the collar.
10. Fold twice to obtain a square.

2

3

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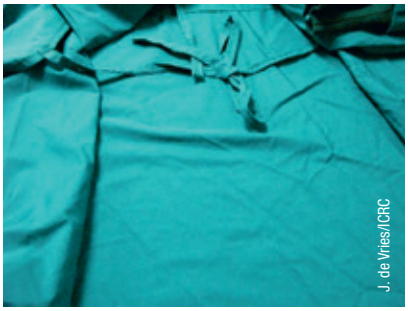

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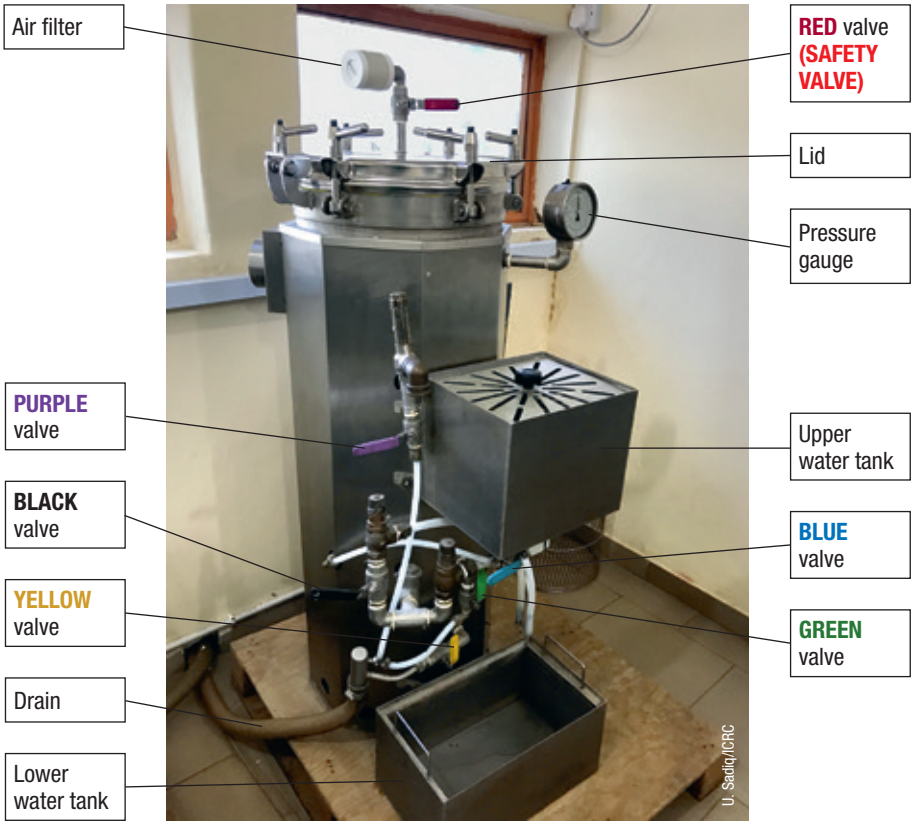
APPENDIX VI
OPERATING INSTRUCTIONS: 90-LITRE AUTOCLAVE

Sterilization with 90-litre autoclave

- Autoclave designed for hospitals in low-resource settings
- Can be used with a variety of power sources (electricity/gas/kerosene)
- Has an incorporated drying system (by condensation) specifically designed for use without electricity



Tips

- A valve is open when its handle is in line (or parallel) with its piping.
- A valve is closed when its handle is at right angles (or perpendicular) to the pipe.

YELLOW = water drain valve –
USE EXTREME CAUTION WHEN OPENING THE YELLOW VALVE

RED = air release valve **(SAFETY VALVE)**

BLUE = cooling water valve

BLACK = pressure selection valve –
MUST BE CLOSED FOR STERILIZATION AT 2 BAR (134°C)

GREEN = steam release valve

PURPLE = purge valve

If your autoclave does **NOT** have a **PURPLE** handle/valve – the **GREEN** handle/valve must be used instead.

Preparation

1. Close the **YELLOW**, **RED**, **GREEN** and **BLUE** valves (handle must be perpendicular to the pipe).
2. Leave the **PURPLE** valve open (handle must be parallel to the pipe).
3. Pour 16 litres of clean water into the autoclave. The outer water tank can be used as a measure (fill up to the line = 16 litres).
4. Place the items to be sterilized in the basket(s), separating them so that the steam can easily circulate between them (leave enough space for a hand to slide between the packages).
5. Avoid overloading the baskets (maximum 75% of capacity).
6. Place a clean absorbent cloth or crepe paper over the load to absorb condensation drops falling from the inside of the lid.
7. Close the lid and tighten the bolts in diametrically opposed pairs. Make sure all the bolts are tightened.
8. Close the **BLACK** valve for an operating pressure of 2.2 bar (134°C) for your sterilization cycle (handle must be perpendicular to the pipe).

Heating

9. Turn the heating on and up to the maximum setting; turn the dial to position 3 when using electric heating.

Purging

10. When a continuous jet of steam escapes from the exhaust piping (continuous for 5 minutes), close the **PURPLE** valve (handle must be perpendicular to the pipe).
11. The pressure inside the chamber will start to rise. When the pressure reaches 1 bar on the pressure gauge (first red line), open the **PURPLE** valve (handle must be parallel to the pipe).
12. Let the pressure fall to about 0.2 bar, then close the **PURPLE** valve.
13. Repeat steps 11 & 12 two more times to eliminate all air pockets.

Sterilization

14. The pressure must now rise to between 2.0 and to 2.2 bar (134°C).
15. When the pressure reaches 2.2 bar, the control valve starts to release steam.
16. Now start the timer for your sterilization cycle; **18 or 25 minutes**.
17. Reduce the heat (turn the dial to position 2) to maintain the release of a small amount of steam.
18. Check the pressure regularly and adjust the heat if necessary.

Expelling steam and water

19. When the sterilization period is complete **(18 or 25 minutes)**, turn the dial to position 0, which turns the heat off.
20. Open the **YELLOW** valve (handle must be parallel to the pipe).

CAUTION
When opening the YELLOW valve, a jet of boiling water and steam will be released. A flexible tube to vent this boiling water and steam must be used. Ensure the boiling water is directed into a safe area, e.g. into a metal sewer drainage hole or safe area outside.

21. When the pressure drops to 0.1 bar, close the **YELLOW** valve (handle must be perpendicular to the pipe).

Drying

22. Fill the upper tank with **cool** water (16 litres). The cooler the water, the more effective the drying process.
23. Open the **BLUE** valve (handle must be parallel to the pipe). The cool water will flow into the autoclave passing through the cooling coil and will then collect in the lower water tank. This process takes about 10 minutes.
24. The remaining steam in the chamber will condense, and a vacuum is created that will dry the load. The pressure will start to fall as the vacuum is created.
25. The pressure will drop to about -0.8 bar. The vacuum must be maintained for **30 minutes**.
26. After 30 minutes, close the **BLUE** valve (handle must be perpendicular to the pipe).
27. Break the vacuum by opening the **RED** valve (handle must be parallel to the pipe). This allows air to enter the chamber and the pressure will increase to atmospheric pressure with the pressure gauge reading 0 bar. This process can take up to 2 minutes.
28. The autoclave lid can now be opened. This must be done slowly and carefully as any remaining steam may scald you.
29. Remove the cloth or crepe paper from on top of the load.
30. Wait a few minutes before taking out the basket(s).
31. Remove the basket(s) and place it/them on a flat workspace covered with a clean reusable drape or single use surgical drape.

Checking

32. The packages must be cooled down before they are taken to the storage area. Wire racks are ideal as they allow ventilation of the packages while they cool down.
33. Check that the packages are intact with no tears. Discard any wet packages, they will need to be re-packaged and re-sterilized.
34. Replace the lid on the autoclave, leaving it slightly open.

Storage and distribution

35. Transfer the sterile packages to the storage area.

Remarks

- A filter must be used. If you do not have these in your facility, cotton wool or gauze compresses can be used instead (to filter the air reintroduced into the autoclave). Change the cotton every 50 cycles or once a month, whichever comes first.
- The heating dial has three positions. These indicate how much power is used and how much heat is applied to the chamber:
  - Position 3 (4,500 W) – to heat the water to boiling point.
  - Position 2 (3,000 W) – to maintain the steam supply during sterilization.
  - Position 1 (1,500 W) – used when there is an insufficient electrical supply. A supplementary heating source is required when using this position, e.g. a gas burner or wood fire.
- Instrument drums are NOT recommended. However, if drums are the only option, the sliding windows must be open during the sterilization cycle. Once they have been removed from the autoclave, the sliding windows MUST BE CLOSED IMMEDIATELY.

APPENDIX VII
INSTRUCTIONS FOR LOADING AND UNLOADING A TOP-LOADING VERTICAL AUTOCLAVE WITHOUT VACUUM PUMP (E.G. 90-LITRE)

LOADING	UNLOADING
• Loads must be homogeneous, either instruments or linen. They must NOT be put in the same load together. • When placing the packages in the basket, do not pack them too tightly. Steam must be able to circulate freely. • Fill the lower basket first; small packages can be placed vertically, but instrument sets packaged in wire baskets should be placed horizontally. • Do not overload the lower basket; none of the packages should extend beyond the top of the basket. If this occurs, the upper basket may damage items in the lower load by tearing the crepe paper (which is fragile). • For each basket, place a Class 6 TST strip, wrapped in a double layer of crepe paper, in the middle of the load. • Cover the top basket with a piece of linen cloth or crepe paper.	• Wait until the end of the sterilization cycle. • Let the autoclave cool down and the drying finish before opening the autoclave. • Put on heat-resistant gloves. • Remove the crepe paper or linen cloth that was placed under the lid. • Empty the autoclave baskets, placing the packages on a clean, dry surface. • Check to make sure the wrapping is intact and dry. • Unwrap the Class 6 TST strip and check that it has changed colour. • Complete the sterilization logbook: add the Class 6 TST strip and write the date, cycle number, type of load, signatures and any comments.

APPENDIX VIII
OPERATING INSTRUCTIONS: 45-LITRE AUTOCLAVE (PRESSURE COOKER)

Sterilization with 45-litre autoclave (pressure cooker)

- Autoclave designed for use in very low-resource settings
- Can be used with a variety of heat sources (e.g. wood fire or gas)
- Must be used at 2.1 bar to achieve 134°C for sterilization

Tips

- A valve is open when its handle is in line (or parallel) with its piping.
- A valve is closed when its handle is at right angles (or perpendicular) to the pipe.
- **RED** – air release valve **(SAFETY VALVE)**

Preparation

1. Pour **3.5 litres** of water into the autoclave pot.
2. Place the items to be sterilized in the basket, separating them so that the steam can easily circulate between them (leave enough space for a hand to slide between the packages).
3. Avoid overloading the basket (maximum 2/3 of capacity).
4. Place a clean absorbent cloth or crepe paper over the load to absorb condensation drops falling from the inside of the lid.
5. Close the lid and tighten the bolts (tighten in diametrically opposed pairs).

Heat

6. Set up the heating source while ensuring the autoclave is in a stable position.
7. The **RED** valve must be in the open position.
8. Turn the heating on and up to the maximum setting.
9. When a continuous jet of steam escapes from the **RED** valve, close the valve.

Purging

10. When the pressure reaches 1 bar on the pressure gauge, open the **RED** valve.
11. Let the pressure fall to 0.2 bar and then close the **RED** valve.
12. Repeat steps 10 & 11 two more times to eliminate all air pockets.

Sterilization

13. As soon as the pressure reaches 2 bar, start timing the sterilization process **(18 or 25 minutes)**.

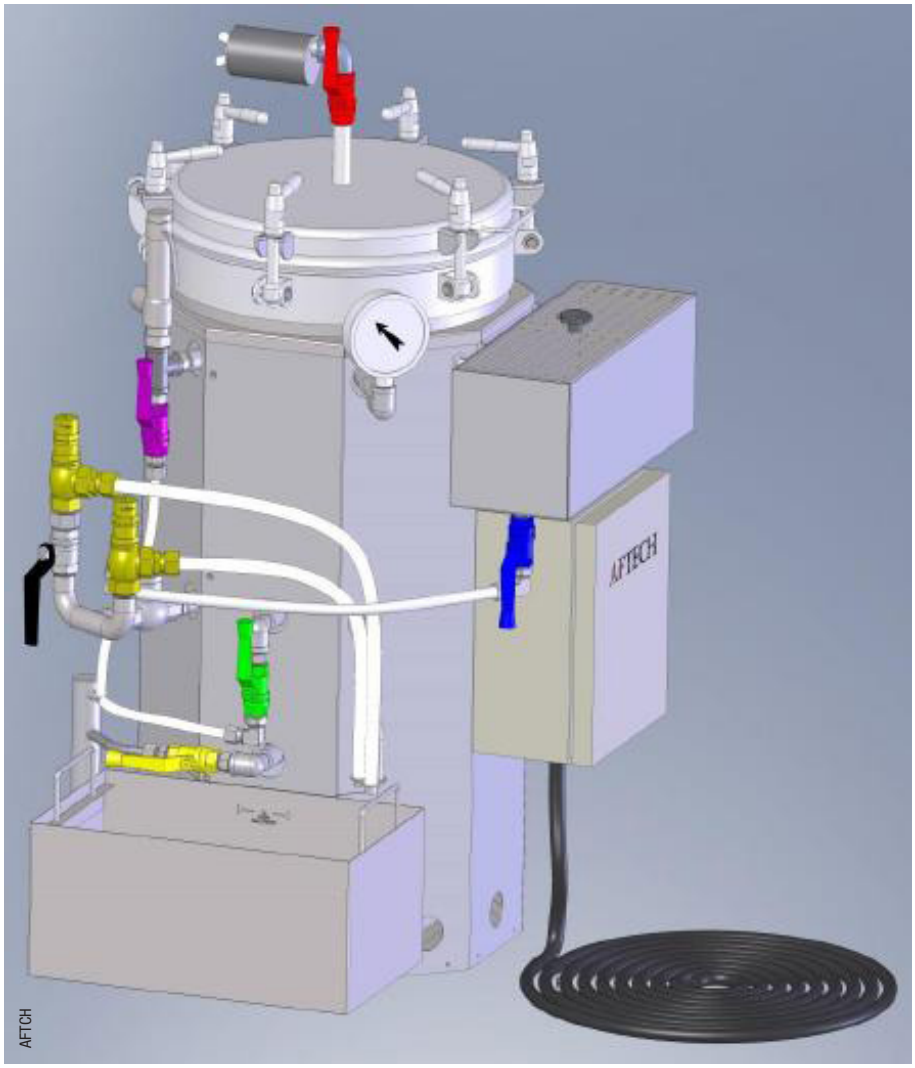
Drying

14. When the sterilization time is up, turn off the heat.
15. Open the **RED** valve and let the pressure fall to 0.2 bar. Then close the **RED** valve.
16. Wait for 30 minutes to allow the autoclave to cool down – the lid must be kept closed at this stage.
17. Open the **RED** valve to return the autoclave to atmospheric pressure (0 bar).
18. Undo the bolts and open the lid slowly and carefully (to avoid being scalded by steam).
19. Remove the basket and place it on a clean workspace to check the packages are dry and intact.

APPENDIX IX
OPERATING INSTRUCTIONS: 45-LITRE AUTOCLAVE (MINI)

Sterilization with 45-litre autoclave (mini)

- Autoclave designed for hospitals in low-resource settings
- Can be used with a variety of power sources (electricity/gas/kerosene)
- Has an incorporated drying system (by condensation) specifically designed for use without electricity
- The 45-litre mini autoclave is a scaled down version of the 90-litre version – the only difference is that it has one basket
- Instructions for the 45-litre autoclave are the same as for the 90-litre version
- Must be used at 2.1 bar to achieve 134°C for sterilization
- *See Appendix VI for detailed operating instructions.*

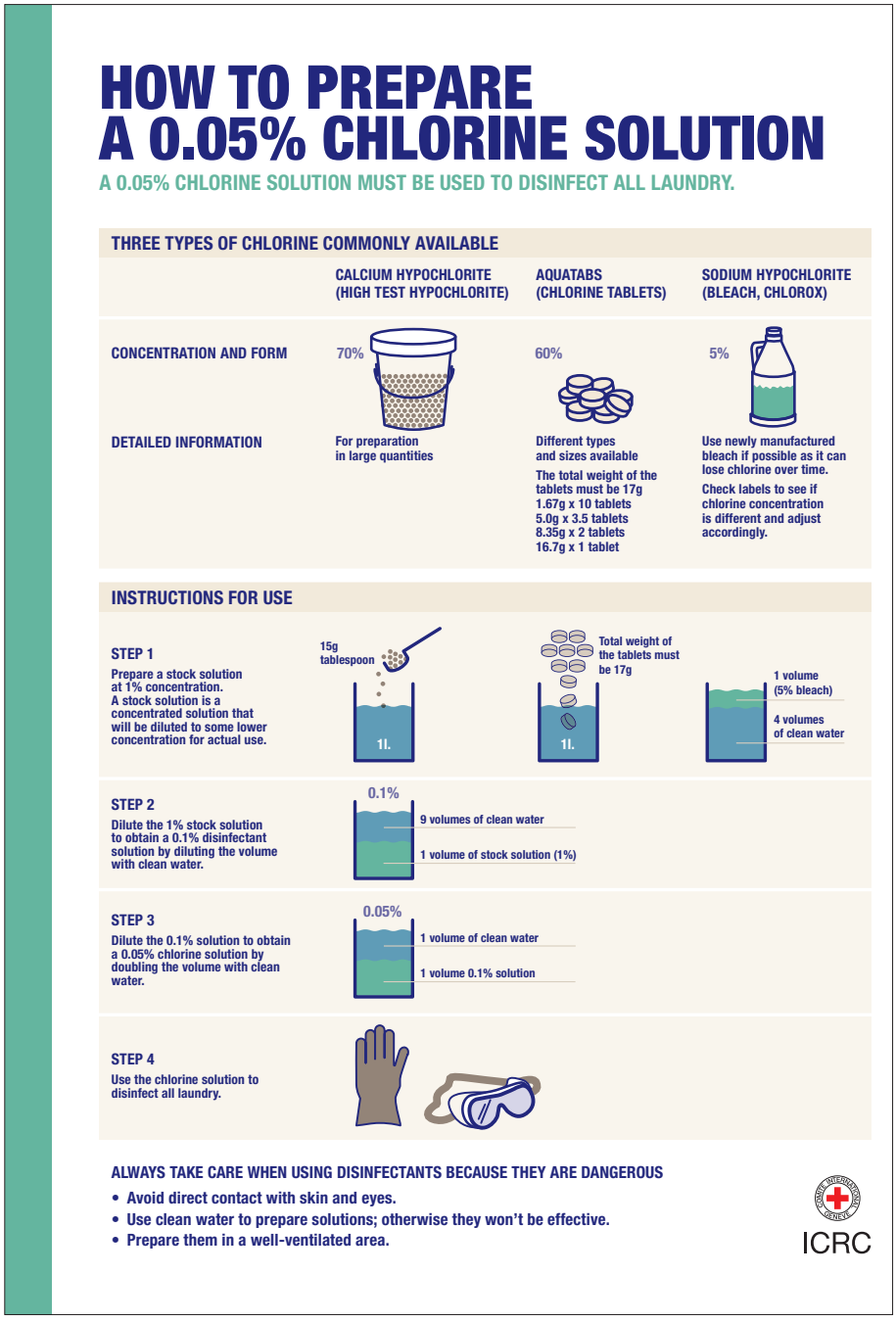


APPENDIX X
INSTRUCTIONS FOR LOADING AND UNLOADING A FRONT-LOADING HORIZONTAL AUTOCLAVE WITH VACUUM PUMP (WITH OR WITHOUT STEAM GENERATOR)

LOADING	UNLOADING
• Loads must be homogeneous, either instruments or linen. • Fill the chamber to two-thirds full. • When placing the packages, do not pack them too tightly. Steam must be able to circulate freely. • Place the packages on the autoclave shelf making sure the packages do not touch the walls of the autoclave chamber. • Place a Class 6 TST strip, wrapped in a double layer of crepe paper, in the middle of the load.	• Wait until the end of the sterilization cycle. • Let the autoclave cool for 15 minutes. • Put on heat-resistant gloves. • Empty the autoclave, placing the packages on a clean, dry surface. • Check to make sure the wrapping is intact and dry. • Unwrap the Class 6 TST strip and check that it has changed colour. • Remove the sterilization cycle graph or the printed ticket from the printer and check that it matches the reference graph. Write the date and cycle number on the paper and archive it. • Complete the sterilization logbook: add the Class 6 TST strip and write the date, cycle number, type of load, signatures and any comments.

APPENDIX XI
INSTRUCTIONS ON HOW TO PREPARE 0.05% CHLORINE SOLUTION FOR WASHING LAUNDRY

A 0.05% chlorine solution must be used to disinfect all laundry after the initial washing process. This chlorine solution must be used for both hand washing or machine washing of laundry.


HOW TO PREPARE
A 0.05% CHLORINE SOLUTION
A 0.05% CHLORINE SOLUTION MUST BE USED TO DISINFECT ALL LAUNDRY.
THREE TYPES OF CHLORINE COMMONLY AVAILABLE
CALCIUM HYPOCHLORITE (HIGH TEST HYPOCHLORITE)
AQUATABS (CHLORINE TABLETS)
SODIUM HYPOCHLORITE (BLEACH, CHLOROX)
CONCENTRATION AND FORM
70%
60%
5%
DETAILED INFORMATION
For preparation in large quantities
Different types and sizes available
The total weight of the tablets must be 17g
1.67g x 10 tablets
5.0g x 3.5 tablets
8.35g x 2 tablets
16.7g x 1 tablet
Use newly manufactured bleach if possible as it can lose chlorine over time.
Check labels to see if chlorine concentration is different and adjust accordingly.
INSTRUCTIONS FOR USE
STEP 1
Prepare a stock solution at 1% concentration. A stock solution is a concentrated solution that will be diluted to some lower concentration for actual use.
15g tablespoon
1l.
Total weight of the tablets must be 17g
1l.
1 volume (5% bleach)
4 volumes of clean water
STEP 2
Dilute the 1% stock solution to obtain a 0.1% disinfectant solution by diluting the volume with clean water.
0.1%
9 volumes of clean water
1 volume of stock solution (1%)
STEP 3
Dilute the 0.1% solution to obtain a 0.05% chlorine solution by doubling the volume with clean water.
0.05%
1 volume of clean water
1 volume 0.1% solution
STEP 4
Use the chlorine solution to disinfect all laundry.
ALWAYS TAKE CARE WHEN USING DISINFECTANTS BECAUSE THEY ARE DANGEROUS
• Avoid direct contact with skin and eyes.
• Use clean water to prepare solutions; otherwise they won't be effective.
• Prepare them in a well-ventilated area.
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APPENDIX XII
INSTRUCTIONS FOR PREPARING SURFANIOS

Surfanios is a detergent/disinfectant that is used to disinfect all surfaces: floors, walls and medical equipment (e.g. mayo table, operating table, operating lamp). It is non-corrosive and compatible with any kind of covering/flooring.

Concentrated Surfanios solution must be diluted to **0.25%** for use as a cleaning solution.

Equipment needed

- Bucket or basin
- Clean water (for preparing the solution)
- Surfanios detergent/disinfection solution
- Timer
- PPE – apron, gloves, mask and goggles must always be worn when using this product

Avoid contact with skin and eyes; in case of contact, rinse immediately and thoroughly with clean water and seek medical advice.

Technique for preparing Surfanios solution

1. In a bucket or basin put the required amount of clean water.
2. Add Surfanios solution in accordance with the dosing table below.
3. Stir until the solution is completely mixed.
4. Set the timer for 15 minutes.
5. After 15 minutes the Surfanios solution is ready to be used.

After the Surfanios concentrate has been mixed in, the solution **MUST** rest for 15 minutes before it can be used.

DOSING TABLE TO PREPARE A 0.25% SOLUTION OF CONCENTRATED SURFANIOS SOLUTION	
Amount of solution required	**Amount of concentrated Surfanios**
1 litre water (e.g. beds, medical devices)	2.5 ml
2 litres water (e.g. beds, medical devices)	5 ml
4 litres water (e.g. floors, walls)	10 ml
8 litres water (e.g. floors, walls)	20 ml
12 litres water (e.g. floors, walls)	30 ml

For ease of use, the Surfanios bottle neck has lines printed on it to show the amount of solution in millilitres.

A. Cretu/ICRC

E. Reyniers/ICRC

PROCEDURE FOR CLEANING

Equipment needed

- 2 buckets (different colours):
  - 1 bucket for the diluted Surfanios solution
  - 1 bucket for clean cold water
- 1 clean cloth or mop

Technique

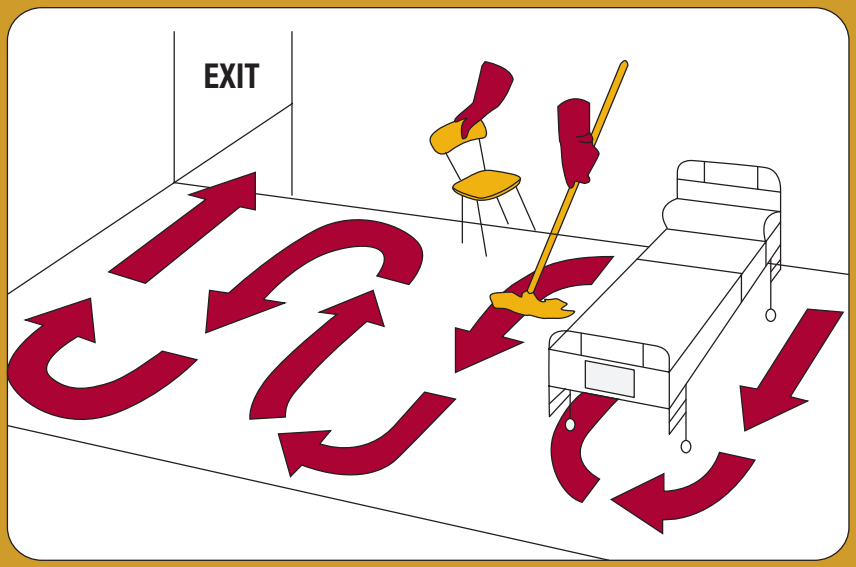
Work from the cleanest to the dirtiest surface and from top to bottom.

Surfaces and furniture

Immerse the cloth or mop in the bucket of diluted Surfanios solution, wring it out to remove excess solution and wipe the furniture.

When cleaning:
- the floor – clean from the back to the exit of the room
- the walls – clean from the top to the bottom and from the back to the exit
- a cupboard – clean from the top to the bottom and from the back to the front
- a bed – clean first the mattress (head to foot) and then the bed frame from top to bottom.

If necessary, rinse the cloth or mop in the bucket of clean water and wring it out before immersing it again in the solution.



Do not rinse. Leave everything to dry for 15 minutes. Do NOT enter the room, except in an emergency.

After cleaning

1. Keep the remaining Surfanios solution for the next cleaning session.
2. Empty the water bucket.
3. Rinse the bucket and mop with Surfanios solution.
4. Let them dry before reusing.

At the end of each day

1. Clean and rinse all cleaning equipment with Surfanios.
2. Let it dry.
3. Discard the remainder of the Surfanios solution.

Once a month, all surfaces should be cleaned with an ammoniated detergent (e.g. Ajax (Colgate Palmolive)) to remove the fat layer that is formed by the successive application of Surfanios.

Demonstration of cleaning

APPENDIX XIII
INSTRUCTIONS: BOWIE–DICK TEST WHEN USING AN AUTOCLAVE WITH VACUUM PUMP

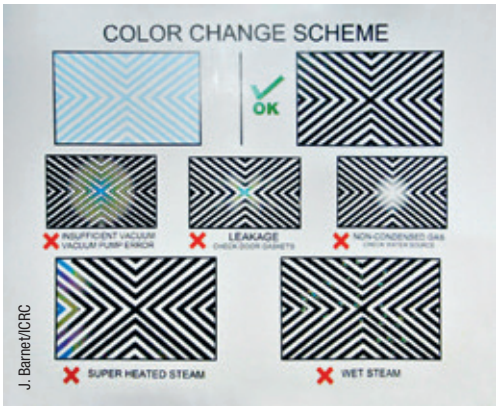
THE BOWIE–DICK TEST CHECKS THE AIR-REMOVAL SYSTEM OF THE AUTOCLAVE

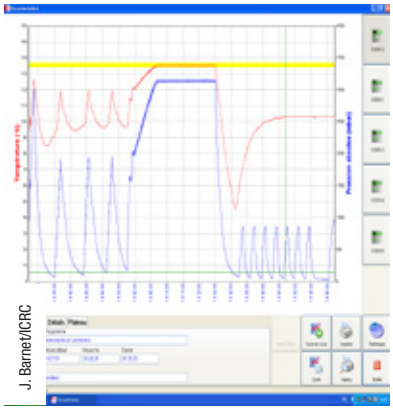
If your facility has an autoclave with vacuum pump, then the "Bowie–Dick Test" must be performed every day (when the sterilizer is being used) before the first load (in an empty autoclave). The Bowie–Dick Test is performed to assess air-removal efficiency in steam sterilizers used in pre-vacuum sterilization cycles.

Technique

- A package of 100% cotton surgical towels must be made with a Bowie–Dick Test sheet placed in the centre of the package.
- The test package is placed horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber.
- The test must be run at 134°C for 3.5 minutes.
- Air that is not removed from the chamber will interfere with steam contact.
- Sterilizer vacuum performance is acceptable if the sheet inside the test package shows a uniform colour change. Entrapped air will cause a spot to appear on the test sheet, because the steam is unable to reach the chemical indicator.
- If the sterilizer fails the Bowie–Dick test, the autoclave must NOT be used until it has been inspected by the sterilizer maintenance personnel and passes the Bowie–Dick Test.

Process challenge devices (which are smaller disposable test packages) can be used for testing, instead of the folded stacked surgical towels. These are designed to simulate the folded stack of surgical cotton towels used during the Bowie–Dick Test. The Bowie–Dick Test does not replace the use of Class 6 TST strips in every load.





READING THE GRAPH FOR A VACUUM-PUMP AUTOCLAVE

When reading the graph, you are checking to see that:

1. the three vacuum peaks are visible
2. the time exposure is correct
3. the "sterilization plateau" is parallel for temperature and pressure.

Once all these checks have been performed and passed, the autoclave may be used.

The Bowie–Dick Test is **ONLY** used on automated autoclaves. It must **NOT** be used in the 90-litre autoclave.

ACKNOWLEDGEMENTS

I would like to express my deepest gratitude to everyone who helped and supported me throughout the process of reviewing and updating the *Sterilization Guidelines*.

Special thanks go to the authors of the first and second editions of these guidelines, Jenny Hayward-Karlsson and Jeannette de Vries. Their dedication and hard work produced an excellent resource that many of us depend on in the field, and on which this present update is based.

I would like to thank all those who helped me with the review and without whose professional support this undertaking would have been impossible. I am extremely grateful to Rodrigo Acosta and Federico Sittaro for their technical advice and support. A special thank you to all my colleagues in the field, who were always willing to help with my many questions, as well as numerous requests for photographs. Thank you!

A special mention goes to Susanne Serry, who provided continual support and technical advice throughout this review process.

To all of you, I extend my most sincere thanks.

Angela Neville

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International Committee of the Red Cross
19, avenue de la Paix
1202 Geneva, Switzerland
T +41 22 734 60 01
shop.icrc.org
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4218/002 11.2020 Cover photo: N. Moon/ICRC